DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 14, 2014

Smith and Nephew, Incorporated
Ms. Shereen Bienz
Senior Regulatory Affairs Specialist
7135 Goodlet Farm Parkway
Cordova, Tennessee 38018

Re: K141471
Trade/Device Name: Journey II XR Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Regulatory Class: Class II
Product Code: JWH
Dated: October 16, 2014
Received: October 17, 2014

Dear Ms. Bienz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Premarket Notification**
**Indications for Use Statement**

510(k) Number (if known): K141471

Device Name: Journey II XR Knee System

Indications for Use:

Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis; failed osteotomies, unicompartmental replacement, or total knee replacement.

The Journey II Total Knee system components are indicated for use only with cement and are single use devices.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

We are smith&nephew

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|---|---|
| **Submitted by:** | Smith & Nephew, Inc.<br>Orthopaedic Division<br>1450 East Brooks Road<br>Memphis, Tennessee 38116 |
| **Date of Summary**: | November 12, 2014 |
| **Contact Person and Address:** | Shereen Bienz<br>Senior Regulatory Affairs Specialist<br>T (901) 399-6325<br>F (901) 566-7075 |
| **Name of Device**: | Smith & Nephew, Inc. Journey II XR Knee System |
| **Common Name**: | Knee Prosthesis |
| **Device Classification Name and Reference**: | 21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis |
| **Device Class**: | Class II |
| **Panel Code**: | Orthopaedics/87 |
| **Product Code:** | JWH |

**Device Description**

Subject of this Traditional Premarket Notification are the Journey II XR Knee system. The subject device is a bi-cruciate retaining total knee system which provides the ability for greater flexion to those patients who have the anatomical capability to allow a greater flexion range. Components of this premarket notification include the following components:

- Medial and lateral cross-linked polyethylene articular inserts which will be available in left and right hand
- Titanium alloy (Ti-6Al-4V) tibial bases which will be available in left and right hand

The Journey II XR Knee system will use existing Journey II CR femoral components and existing patella components compatible with the Journey II CR femoral as well as device specific instruments.

**Technological Characteristics**

A review of the mechanical data indicates that the Journey II XR Knee System is capable of withstanding expected *in vivo* loading without failure. The following mechanical testing of the Journey II XR Knee system was performed:

- Tibiofemoral Contact Area Analysis
- Tibiofemoral Constraint Testing
- Construct Fatigue Strength Testing
- Static testing of the insert locking mechanism
- Tibial base plate fatigue performance

A review of this testing has demonstrated that there are no new issues related to the safety and effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices

**Intended Use**

Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis; failed osteotomies, unicompartmental replacement, or total knee replacement. The Journey II Total Knee system components are indicated for use only with cement and are single use devices.

**Substantial Equivalence Information**

The substantial equivalence of the Journey II XR Knee system is based on its similarities in indications for use, design features, and operational principles to the predicate systems listed in the following table.

Table 1: Comparison to Substantially Equivalent Devices

| Design Aspect Reviewed | Journey II XR Knee System | Townley Total Knee (BioPro) | Journey II CR | Genesis II CR | Genesis II High Flex Inserts |
|---|---|---|---|---|---|
| **510(k) Number** | Subject 510(k) | K904448 | K121443 | K951987 | K041825 |
| **Manufacturer** | Smith & Nephew, Inc. | BioPro, Inc | Smith & Nephew, Inc. | Smith & Nephew, Inc. | Smith & Nephew, Inc. |
| **Similar Indications for Use** | Yes | Yes | Yes | Yes | Yes |
| **Similar Sterilization Methods** | Yes | Yes | Yes | Yes | Yes |
| **Bi-cruciate retaining** | Yes | Yes | No | No | No |
| **Insert material** | XLPE | UHMWPE | XLPE and UHMWPE | UHMWPE | UHMWPE |
| **Similar Locking Mechanism** | Yes | Yes | Yes | Yes | Yes |
| **Tibial base material** | Ti-6Al-4V | Ti-6Al-4V | Ti-6Al-4V | Ti-6Al-4V | Ti-6Al-4V |
| **Similar Manufacturing Process** | Yes | Unknown | Yes | Yes | Yes |

**Conclusion**

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the Journey II XR Knee System. Based on the similarities to the predicate components and a review of the validation testing performed, the device is substantially equivalent to above predicate systems.